

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

IN RE VALSARTAN, LOSARTAN, AND
IRBESARTAN PRODUCTS LIABILITY
LITIGATION

MDL No. 2875 (RBK/JS)

MTD OPINION 2

This Document Relates to All Actions

KUGLER, United States District Judge:

Before this Court are Defendants' Motions to Dismiss (Doc. No. 520, 522, 523) the three Master Complaints filed in this Multi-District Litigation ["MDL"] which involves the sale of a generic blood pressure medication that was found to be contaminated with probable human carcinogens. Because the MTDs seek dismissal of several claims for each set of plaintiffs, the Court is issuing a series of opinions to resolve the motions. Each opinion will be numbered with this opinion being the second in the series. This OPINION 2 resolves Defendants' arguments relating to Article III standing. An ORDER 2 of this date accompanies this OPINION 2.

1.0 BACKGROUND AND FACTS¹

Hundreds of millions of Americans suffer from high blood pressure. Two common medications used to treat this condition are Diovan and Diovan HCT and Exforge and Exforge HCT. This case involves their generic counterparts, Valsartan and its combination therapy with hydrochlorothiazide and Amlodipine-valsartan and its combination therapy with hydrochlorothiazide (collectively the valsartan-containing drugs or "VCDs"). While generic drugs are supposed to be bioequivalent to their brand-name counterparts, at some point these VCDs were found to be contaminated with probable human carcinogens known as N-nitrosodimethylamine ("NDMA") and N-nitrosodiethylamine ("NDEA"). This led to a recall of the VCDs in July of 2018. The current lawsuits stem from the Defendants' manufacturing, promotion, and sale of the VCDs and their subsequent recall. Plaintiffs, consumers and Third-Party Payors who purchased or made reimbursements for Defendants' contaminated VCDs, brought an economic damage and a medical monitoring class action against Defendants. They also brought a personal injury action against Defendants. The Defendants are entities with various and sometimes

¹When evaluating a motion to dismiss under Rule 12(b)(1) for lack of standing we must accept as true all material allegations of the complaint and construe them in favor of the plaintiff. *Danvers Motor Co., Inc. v. Ford Motor Co.*, 432 F.3d 286, 288 (3d Cir. 2005) (quoting *Conte Bros. Auto., Inc. v. Quaker State-Slick 50, Inc.*, 165 F.3d 221, 224 (3d Cir. 1998)). We therefore will review the facts as alleged by Plaintiffs in their operative complaint.

overlapping roles within the supply chain. They include the manufacturers (“Manufacturer Defendants”) of the drug (both the manufacturers of the active pharmaceutical ingredient and the manufacturers that make the finished drug product), the wholesalers (“Wholesaler Defendants”) who obtain the finished drug product and resell it to retailers, and consumer-level distributors (“Pharmacy Defendants”).

In the wake of the success of the blood pressure medications DIOVAN and EXFORGE, many generic drug manufacturers sought to capitalize on this success by introducing their own generic versions of the Valsartan drug. (Doc. No. 398, Am. ELMC at ¶¶ 217–20). Many of these generic drug manufacturers, like Teva Pharmaceuticals, contracted with other companies to manufacture the active pharmaceutical ingredient (“API”). (*Id.* at ¶¶ 54, 67, 185). Others manufactured the API themselves because they had vertically integrated supply chains. (*Id.* at ¶¶ 48–72). The events underlying this lawsuit occurred at the foreign manufacturing facilities of the API manufacturers.

Defendants ZHP, Aurobindo, Mylan, and Hetero had manufacturing facilities in India or China where the active pharmaceutical ingredient for the VCDs were produced. (*Id.* at ¶¶ 235, 252, 267, 298). Their manufacturing practices and processes resulted in numerous deviations from and violations of the “current Good Manufacturing Practices”—minimum standards established by the FDA that set forth the requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug. (*Id.* at ¶ 233–311). For instance, after the FDA inspected ZHP’s Chuannan facility in July of 2018, it issued a warning letter to ZHP for significant deviations from the cGMPs. (*Id.* at ¶ 244). Specifically, the FDA explained:

ZHP failed to evaluate the potential effect that changes in the manufacturing process may have on the quality of [its] API. More specifically, ZHP approved a [V]alsartan API process change . . . that included the use of the solvent. [ZHP’s] intention was to improve the manufacturing process, increase product yield, and lower production costs. However, [ZHP] failed to adequately assess the potential formation of mutagenic impurities [such as NDMA,] when [it] implemented the new process. Specifically, [it] did not consider the potential for mutagenic or other toxic impurities to form from [redacted] degradants, including the primary [redacted] degradant, [redacted].

(*Id.* at ¶ 246). The FDA’s inspections of the other Defendants’ facilities revealed similar, substantial deviations from the cGMP. (*Id.* at ¶ 233–311).

The introduction of a solvent into the manufacturing process of the VCDs and the manufacturing Defendants’ deviations from the cGMPs created and allowed the presence of two probable human carcinogens—n-nitrosodimethylamine (“NDMA”) and n-nitrosodiethylamine (“NDEA”)—to remain undetected in the VCDs. (*Id.* at ¶¶ 335–53). Around the time that the manufacturers introduced the solvent into their manufacturing process, an FDA inspector found that ZHA “routinely disregarded sampling anomalies suggestive of impurities.” (*Id.* at ¶ 340, 349).

On July 13, 2018, FDA announced the voluntary recalls of the VCDs manufactured by Defendants and others due to the presence of NDMA and NDEA. (*Id.* at ¶ 355). Two weeks later, the FDA announced expanded recalls of additional VCDs manufactured by Defendants and non-parties and repackaged by third parties. (*Id.* at ¶ 356). In a press release issued that same day, the FDA explained the reason for its concern regarding the presence of NDMA found in VCDs:

NDMA has been found to increase the occurrence of cancer in animal studies . . . Consuming up to 96 nanograms NDMA/day is considered reasonably safe for human ingestion . . . The amounts of NDMA found in the recalled batches of valsartan exceeded these acceptable levels.

(*Id.* at ¶ 321). Subsequently, the FDA announced numerous additional recalls of VCDs, and other similar products manufactured, distributed, or sold by Defendants as well as non-parties (*Id.* at ¶ 358).

After the recall of ZHP's VCDs, FDA testing revealed the valsartan API manufactured by ZHP contained levels of NDMA of between 15,180 and 16,300 ng, which was in excess of the FDA's interim limits of 96 ng/day or 0.3 ppm. *Id.* at ¶ 250.. Similarly, FDA testing showed the valsartan API manufactured by ZHP for Torrent Pharmaceuticals contained levels of NDEA of up to 1,310 ng in excess of the FDA's interim limits of 26.5 ng/day or 0.083 ppm. *Id.* at ¶ 251. The FDA's testing of the other Defendants VCDs revealed similar findings of NDMA and NDEA well in excess of the limits. *Id.* at ¶ 266, 297, 311.

Lawsuits quickly followed these voluntary recalls. Consumers and third-party payors filed a class action alleging economic losses. (Doc. No. 1). Consumers also filed a medical monitoring class action alleging "cellular damage, genetic harm, and/or an increased risk of developing cancer" as a result of exposure to the probable human carcinogens in the VCDs. ECF Doc. 123. Lastly, personal injury claims were filed on behalf of consumers who allegedly developed cancer as a result of taking the contaminated VCDs. (Doc. No. 122). These actions were centralized by the United States Judicial Panel on Multi-District Litigation and transferred to this Court for pretrial purposes only. ECF Doc. 1.

Three Master Complaints were filed with this Court. ECF Doc. 122 ¶ 4–5; ECF Doc. 123 at 1 n.1; ECF Doc. 398 at ¶ 1 n.1 Only the first two are relevant here.

1.1 Economic Loss Master Complaint

The Economic Loss Master Complaint ("ELMC") alleges economic damages based on Defendants sale of VCDs that were "of a lesser quality and were adulterated and/or misbranded (and thereby rendered worthless) through contamination with" probable human carcinogens. ECF Doc. 398 ¶ 4. The ELMC asserts eighteen claims on behalf of classes of consumers and third-party payors in order to recoup the amounts they paid for Defendants' allegedly worthless VCDs. In the EMLC, the consumer class plaintiffs are represented by twenty-four named Plaintiffs from the following states: (1) New York; (2) New Mexico; (3) North Carolina; (4) South Carolina; (5) New Jersey; (6) Texas; (7) Indiana; (8)

Pennsylvania; (9) California; (10) Ohio; (11) Massachusetts; (12) Mississippi; (13) Florida; (14) Virginia; (15) Louisiana; (16) Kansas; (17) Georgia; and (18) Connecticut. ECF Doc. 398, Am. ELMC ¶¶ 11–34. The named Plaintiffs allege they purchased one or more of Defendants' VCDs, that Defendants expressly and impliedly warranted their VCDs were the same as the registered listed drug, had they known the product was not the same as the brand-name drug, they would not have paid for it, and had Defendants' deception about the product's impurities been made known earlier, they would not have paid for it. (*Id.*). The named Plaintiffs alleged they purchased the VCDs from the following: (1) ZHP; (2) Aurobindo; (3) Solco; (4) Mylan; (5) Teva; (6) Camber; (7) Torrent; and (8) Hetero. *Ibid.* The Third-Party Payor Plaintiffs are represented by Plaintiff MSP Recovery Claims, Series LLC ("MSRPC") as they have assigned their recovery rights to assert claims to MSRPC. *Id.* ¶36. MSRPC's assignors paid \$79 million on behalf of their enrollees and it is believed some of those payments include payments for Defendants VCDs. *Id.* ¶13).

Because Defendants VCDs were supposed to be the generics of Diovan® and of the valsartan in Exforge®, they had to demonstrate the medication was the same as the brand name versions in the following ways: (1) the active ingredient in the generic medication is the same as the brand name medication; (2) the generic medication is manufactured under the same strict standards as the brand name medication is; (3) the generic medication has the same strength as the brand name medication; (4) the inactive ingredients of the generic medication are acceptable; and (5) the label is the same as the brand-name label. *Id.* ¶158. These similarities help demonstrate bioequivalence, meaning the generic medication provides the same benefits and functions in the same manner as its brand-name counterpart. *Id.* ¶157. Consistent with these requirements, the FDA prohibits the manufacture and sale of adulterated or misbranded drugs. *Id.* ¶ 162. A drug may be adulterated if: (1) it has been prepared under unsanitary conditions whereby it may have been rendered injurious to health; (2) the methods used in, or the facilities used for, its manufacture do not conform to current good manufacturing practice; (3) it purports to represent a drug the name of which is recognized in an official compendium and its quality or purity falls below the standard set forth in the compendium; and (4) any substance has been mixed or packed therewith so as to reduce its quality or strength. *Id.* ¶165. A drug may also be misbranded if: (1) its labeling is false or misleading; (2) if the labeling does not contain the proportion of each active ingredient; (3) it is an imitation of another drug; (4) it is offered for sale under the name of another drug; and (5) it is advertised incorrectly in any manner. *Ibid.*

The VCDs manufactured by Defendants, according to Plaintiffs' allegations, were adulterated and misbranded because they contaminated with NDMA and NDEA—probable human carcinogens. *Id.* ¶168–76. Their logic is that because the FDA defines an "active ingredient" in a drug as "any component that is intended to . . . affect the structure or any function of the body of man" and NDMA and NDEA have the ability to cause cancer by triggering genetic mutations, i.e., affecting a structure of the human

body, NDMA and NDEA are, by definition, active ingredients in the VCDs. *Id.* ¶ 168–70. Based on this premise, they conclude the VCDs were adulterated and misbranded. *Id.* ¶ 173, 175, 181, 182, 233, 239.

Defendants sought and received inclusion of their VCDs in the Orange Book, which requires them to demonstrate that the VCDs are bioequivalent to the brand-name counterparts. *Id.* ¶ 361. This obligation of bioequivalence is ongoing. (*Id.* at ¶ 362). Likewise, Defendants VCDs were accompanied by an FDA-approved label, which Plaintiffs allege, constitutes a representation and warranty by Defendants that their VCDs are the same as their brand name counterpart. *Id.* ¶ 363. Defendants also represented and warranted that the VCDs were the same as and therapeutically equivalent to the brand name counterparts by introducing the VCDs into the US market. *Id.* ¶ 364. Further, each Defendant affirmatively misrepresented and warranted to consumers and TPP through their websites, brochures, and other marketing or informational materials that the VCDs complied with current good manufacturing practices and did not contain any ingredients besides those listed on the FDA approved labels. *Id.* ¶ 365.

Plaintiffs allege the voluntary recalls caused them direct economic loss because they “paid to replace the recalled VCDs with substitute drugs, effectively paying twice for drugs intended to treat the same medical conditions and for use over the same (or an overlapping) time period, when they should only have paid once.” *Id.* ¶ 359. Likewise, Plaintiffs further allege:

[a]dulterated, misbranded, and/or unapproved VCDs contaminated with cancer-causing compounds are essentially worthless. No reasonable consumer (including Plaintiffs) would purchase (or reimburse for) these nitrosamine laden VCDs. Nor could they, as an adulterated, misbranded, and/or unapproved VCD cannot even be legally sold or purchased within the United States. At a minimum, adulterated, misbranded, and/or unapproved VCDs were worth less than their non-contaminated equivalents. . . . [m]oreover, every consumer . . . who purchased and ingested a VCD, including Plaintiffs . . . has been exposed to a non-bargained for carcinogen agent with mutagenic properties that operates at the cellular and sub-cellular levels, and may give rise to future potential health consequences.

Id. ¶ 371–72. In the midst of the recalls, the “FDA advised patients to continue taking VCDs . . . because of the risks associated with untreated high blood pressure.” *Id.* ¶ 373. However, “because of the seriousness of the impurity . . . all or virtually all patients immediately stopped taking the tainted drug products after receiving notice of the recall. They were prescribed a safe alternative. VCDs had no use and were discarded.” *Id.* ¶ 375.

1.2 Medical Monitoring Master Complaint

The Medical Monitoring Master Complaint (“MMMC”) alleges “cellular damage, genetic harm, and/or . . . an increased risk of developing cancer” based on ingestion to Defendants’ contaminated VCDs. ECF Doc. 123 ¶ 1. It asserts nine claims seeking “injunctive and monetary relief, including creation of a fund to finance independent medical monitoring services, . . . notification to all people exposed to this contamination, examinations, testing, preventative screening, and care and treatment

of cancer resulting, at least in part, from the exposure to the NDMA or NDEA contamination.” (*Id.*). The consumer class plaintiffs are represented by ten named Plaintiffs from the following states: (1) California; (2) Florida; (3) Illinois; (4) Maryland; (5) New Jersey; (6) Pennsylvania; and (7) West Virginia. *Id.* ¶¶9–19. Each was prescribed and used varying doses of Defendants’ VCDs for several years and allege that as a result of the VCDs being contained with NDMA and NDEA they suffered cellular and genetic injury that creates or increases the risk that they will develop cancer. (*Id.*). The named Plaintiffs allege the following entities were the distributors of their VCDs: (1) Camber; (2) Hetero USA; (3) Hetero Labs; (4) Hetero; (5) Solco; (6) Princeton; (7) Huahai US; (8) ZHP; (9) Walmart; (10) Aurobindo USA; (11) Aurolife; (12) Aurobindo; (13) Actavis; (14) Teva; (15) Mylan Pharm; (16) Mylan Labs; (17) Mylan; and (18) CVS. (*Id.*).

2.0 LEGAL STANDARD

2.1 Federal Rule of Civil Procedure 12(b)(1)

When a defendant challenges whether the facts as pleaded in a complaint create Article III standing pursuant to Federal Rule of Civil Procedure 12(b)(1), it is considered a facial challenge. *Kamal v. J. Crew Grp., Inc.*, 918 F.3d 102, 109 (3d Cir. 2019). With a facial challenge, the Court must construe the alleged facts in the light most favorable to the nonmoving party. *Constitution Party of Pa. v. Aichele*, 757 F.3d 347, 358 (3d Cir. 2014).

2.2 Article III Standing

“Under Article III of the United States Constitution, the power of the judiciary ‘extends only to ‘Cases’ and ‘Controversies’” *Long v. Se. Pa. Transp. Auth.*, 903 F.3d 312, 320 (3d Cir. 2018) [*quoting Spokeo, Inc. v. Robins*, 136 S.Ct. 1540, 1547 (2016)]. “One element of the case-or-controversy requirement is that [plaintiffs], based on their complaint, must establish that they have standing to sue.” *Raines v. Byrd*, 521 U.S. 811, 818, 117 S.Ct. 2312, 138 L.Ed.2d 849 (1997). The standing doctrine “limits the category of litigants empowered to maintain a lawsuit in federal court” and has “developed in our case law to ensure that federal courts do not exceed their authority as it has been traditionally understood.” *Spokeo*, 136 S.Ct. at 1547. To maintain a suit, a “plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.” *Ibid.*

To establish injury in fact, a plaintiff must show that he suffered “an invasion of a legally protected interest” that is “concrete and particularized” and “actual or imminent, not conjectural or hypothetical.” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). For an injury to be “particularized,” it “must affect the plaintiff in a personal and individual way.” *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1548,

194 L. Ed. 2d 635 (2016), as revised (May 24, 2016). Particularization is necessary but not sufficient to establish injury in fact. *Id.* An injury in fact must also be “concrete.” *Ibid.* A “concrete” injury must be “de facto”; that is, it must actually exist. This does not mean, however, that it must always be tangible. *Id.* at 1549. Intangible injuries can be concrete as well. *Ibid.*

The burden of establishing standing rests with the plaintiffs. *Berg v. Obama*, 586 F.3d 234, 238 (3d Cir.2009). In the class action context, the standing inquiry focuses solely on the class representatives. *Mielo v. Steak 'n Shake Operations, Inc.*, 897 F.3d 467, 478 (3d Cir. 2018). In other words, putative class members need not establish Article III standing so long as at least one class representative has standing. *Neale v. Volvo Cars of N. Am., LLC*, 794 F.3d 353, 362 (3d Cir. 2015). Thus, when assessing standing on the basis of the facts alleged in a complaint, this Court must apply the same standard of review used to assess a motion to dismiss for failure to state a claim. *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 243 (3d Cir.2012).

The Third Circuit has described this inquiry as a three-step process. First, we must “tak[e] note of the elements a plaintiff must plead to state a claim”—here, the three elements of Article III standing. *Finkelman v. Nat'l Football League*, 810 F.3d 187, 194 (3d Cir. 2016). Second, we eliminate from consideration any allegations that, “because they are no more than conclusions, are not entitled to the assumption of truth.” *Id.* Third, “where there are well-pleaded factual allegations, [we] assume their veracity and then determine whether they plausibly” establish the prerequisites of standing. *Id.* In conducting this analysis, we are mindful of the Supreme Court's teaching that all aspects of a complaint must rest on “well-pleaded factual allegations” and not “mere conclusory statements.” *Ibid.* To survive a motion to dismiss for lack of standing, a plaintiff “must allege facts that affirmatively and plausibly suggest that it has standing to sue.” ...“Speculative or conjectural assertions are not sufficient. *Ibid.*

3.0 DISCUSSION

The Manufacturer Defendants argue the ELMC and MMMC should be dismissed for lack of Article III standing because: (1) the ELMC does not allege an injury in fact; (2) the MMMC fails to plead injuries fairly traceable to all defendants; and (3) both complaints seek to assert claims under the laws of states in which Plaintiffs do not reside and were not injured. The Wholesaler and Pharmacy Defendants incorporate these arguments.

Plaintiffs maintain both complaints properly allege Article III standing because: (1) the ELMC alleges monetary harm—a paradigmatic form of injury in fact; (2) the MMMC alleges both physical and monetary harm; (3) the injuries alleged are fairly traceable to the Manufacturers based on their misrepresentations; (4) the injuries alleged are fairly traceable to Wholesalers due to their control over the market; and (5) the named class representatives may assert claims on behalf of out of state class members. Each issue will be addressed in turn.

3.1 Article III Standing

3.1.1 Injury in Fact for the Economic Loss Complaint

Defendants maintain the EMLC fails to allege an injury in fact for several reasons. First, they contend there is no allegation of physical harm and the only allegation that comes close— exposure to non-bargained for carcinogens “may give rise to future potential health consequences”—is speculative. Second, Defendants argue there is no allegation that the VCDs stopped working due to the impurity which shows Plaintiffs received the benefit of their bargain. In line with this contention, Defendants characterize the Plaintiffs’ allegation that the VCDs were “worthless” as conclusory. Third and finally, they assert there are no facts alleged from which the Court can value the purported economic injury.

Plaintiffs’ contend their monetary injury resulted from Defendants’ failure to provide the benefit of their bargain. Specifically, Plaintiffs argue they bargained for the benefits of a “generic equivalent [to] Diovan; a pure, unadulterated, and regulatory compliant valsartan generic drug, which would be identical to brand-name valsartan.” Because the VCDs were not as Defendants represented and warranted—that is, they were adulterated, misbranded, non cGMP compliant, and illegal to sell—Plaintiffs did not receive the benefit of their bargain and suffered economic loss by receiving a worthless product.

Economic injury is a paradigmatic form of injury in fact. *Danvers Motor Co., Inc. v. Ford Motor Co.*, 432 F.3d 286, 291 (3d Cir. 2005) (Alito, J.). There are innumerable ways in which an economic injury may be shown. See *In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Practices & Liab. Litig.*, 903 F.3d 278, 281–82 (3d Cir. 2018). However, just as with any theory of injury in fact, mere conclusory or conjectural assertions of economic injury are insufficient. *Id.* at 285. A plaintiff must set forth sufficient factual allegations that, if proven true, would permit a factfinder to not only determine that she suffered at least some economic injury but also “value the purported injury at something more than zero dollars without resorting to mere conjecture.” *Id.* at 288, 285. Under the benefit of the bargain theory, this is accomplished by “alleging [you] bargained for a product worth a given value but received a product worth less than that value.” *Id.* at 283. The economic injury is then calculated as “the difference in value between what was bargained for and what was received.” *Id.*

A line of Third Circuit cases illustrates the contours of this requirement. The first two cases in this lineage are *Finkelman v. National Football League*, 810 F.3d 187 (3d Cir. 2016), and *Cottrell v. Alcon Laboratories*, 874 F.3d 154 (3d Cir. 2017). As the Third Circuit noted “[t]hese precedential opinions represent two sides of the same coin” because they both involved whether a plaintiff’s theory of economic injury was too conjectural to establish standing. *In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Practices & Liab. Litig.*, 903 F.3d 278, 285 (3d Cir. 2018).

Finkelman involved a consumer fraud class action against the National Football League (“NFL”) for its ticketing practices for Super Bowl XLVIII, which allegedly violated New Jersey law. *Finkelman v. Nat’l Football League*, 810 F.3d 187, 188 (3d Cir. 2016). In anticipation of the Super Bowl, the NFL withheld

almost all tickets—99%—from the general public for league insiders and offered the remaining 1% to winners of a lottery that all could enter. *Id.* at 190. One named plaintiff, Josh Finkelman, did not enter the lottery, but instead bought two tickets on a secondary, resale market for \$2,000 per ticket even though they each had a face value of \$800. *Ibid.* He brought a class action on behalf of all persons who paid for tickets in excess of their printed price and alleged they “suffered ascertainable losses consisting of the purchase price of the ticket in excess of the face value.” *Id.* at 197. The Court construed this claim as asserting two possible theories of injury in fact but rejected both; only the second is relevant here. *Id.* at 197–203. The second theory was a basic application of supply and demand—had the NFL not wrongfully withheld tickets, the price of Finkelman’s ticket on the resale market would have been cheaper. *Id.* at 199. While this theory seemed plausible, the Court found it speculative because league insiders had the same incentive to resell their tickets on the secondary market as the unnamed broker who sold his tickets to Finkelman. *Id.* at 200. Thus, it was just as likely that the NFL’s ticket withholding practice actually increased the number of ticket sellers in the secondary market, and consequently decreased the price. *Id.* Accordingly, the Court concluded Finkelman did not have standing because his allegation that he paid more for his tickets than he would have absent the NFL’s alleged misconduct was a “‘bald assertion’ unsupported by well-pleaded facts.” *Id.* at 202.

The problem with the plaintiff’s economic theory in *Finkelman* was that it relied on a speculative inference. This same issue was not present in *Cottrell*. *Cottrell v. Alcon Laboratories*, 874 F.3d 154, 160 (3d Cir. 2017). Consumers of a prescription eye medication brought a class action against the manufacturer alleging it intentionally designed the tip of the bottle dropper to be larger than normal in order to increase the products’ drop size and thereby deplete the medication more rapidly. *Id.* at 160. As a result of this practice, Plaintiffs alleged they suffered substantial economic injury because if the drop size was smaller, the medicine would last longer, and they would spend less on overall. *Id.* The plaintiffs attempted to measure their financial harm by positing two theories; only the first is relevant here. *Id.* at 168. The first theory sought to measure their financial harm by taking the difference in cost between what they would have paid for smaller tipped bottles and what they actually paid for the larger tipped bottles. *Id.* They supported this cost saving allegation through scientific studies which showed how smaller tipped bottles would reduce the number of bottles need for a one-year therapy regime. *Id.* The District Court rejected this theory as being too speculative because it purportedly relied on the presumption that the manufacturers priced their products on volume. *Id.* The Third Circuit found, however, that the pricing theory was not based on this presumption, but rather alleged that smaller tipped bottles would lower the cost of a medication treatment regime by allowing consumers to extract more doses out of the same bottle. *Id.* Thus, because the plaintiffs’ theory was based *solely* on a reduction in the size of the bottle dropper tip, there was no unsupported inferential leap like the one in *Finkelman*. *Id.* at 169

In *In re Johnson*, plaintiff Mona Estrada accused defendants Johnson and Johnson of engaging in unfair and illegal business practices by manufacturing, marketing, and distributing baby powder products without informing consumers that its use may lead to an increased risk of developing ovarian cancer. 903 F.3d 278, 281 (3d Cir. 2018). Her theory of recovery was that she suffered an economic injury by purchasing improperly marketed Baby Powder. *Id.* at 282. Specifically, she alleged had she been properly informed that using Baby Powder could lead to an increased risk in developing cancer, she would not have purchased the powder in the first place. *Id.* The District Court concluded she received the benefit of her bargain and therefore did not suffer an injury in fact because the Baby Powder functioned as intended. *Id.* at 283. On appeal, Ms. Estrada argued that she did not receive the benefit of her bargain because she was promised Baby Powder that was safe but received a product that was not. *Id.* The Third Circuit explained to successfully plead an economic injury under the benefit of the bargain theory a plaintiff must allege that she bargained for a product worth a given value but received a product worth less than that value. *Id.* at 283. Nor would it be enough for a plaintiff to pair a “conclusory assertion of money lost with a request that a defendant pay up.” *Id.* at 288. Because Estrada merely alleged that had she known using Baby Powder could lead to increased risk of cancer, she would not have purchased it, and did not allege the Baby Powder provided her with an economic benefit worth less than what she paid, she did not have Article III standing. *Id.* at 288–90. Her allegation that the Baby Powder was unsafe was equally insufficient because she never alleged that she developed cancer or was at risk of developing it. *Id.* at 289.

More recently, the Third Circuit considered whether the economic injury alleged in a class action against Pep Boy was sufficient for standing in *Thorne v. Pep Boys Manny Moe & Jack Inc.* There the plaintiffs filed a class action against Pep Boys for its failure to help consumers register their tires with manufacturers in violation of 49 C.F.R. § 574.8. *Thorne v. Pep Boys Manny Moe & Jack Inc.*, 980 F.3d 879, 886 (3d Cir. 2020). The plaintiff alleged she did not receive the benefit of her bargain and therefore suffered an economic injury because: (1) she bought tires from Pep Boys that then went unregistered; and (2) unregistered tires are worth less than registered tires as “[c]lass Members not only pay for the tires, but also pay the cost of [d]efendant's compliance with federal law.” *Id.* at 886. The Court concluded the benefit-of-the-bargain theory collided with its case law. *Id.* First, the theory was contrary to *In re Johnson* because the plaintiff's concession that the tires functioned as intended and were not recalled resulted in a conclusory assertion of money lost with a request that defendants pay up. *Id.* at 887. Second, the theory of economic harm conflicted with *Finkelman* because it was speculative whether Pep Boys included the cost of tire-registration compliance in the price of its tires; it was entirely possible that compliance with the registration obligations would not lead to an increase in tire prices as demand might be too elastic. *Id.* As such, the Court concluded the plaintiffs had not alleged a tangible, economic injury that was sufficient to confer standing. *Id.* at 889.

With these principles in mind, we turn to the issue of standing. Although somewhat opaque, the gravamen of Plaintiffs' alleged economic injury is that they did not receive the benefit of their bargain when they purchased Defendants' VCDs because they were contrary to Defendants' warranties and representations—that is, the VCDs were adulterated, misbranded, non cGMP compliant, unlawful to sell, and therefore essentially worthless. For the same reasons, Plaintiffs allege that, at a minimum, the VCDs were worth less than their non-contaminated equivalents. Plaintiffs further allege “the recalls caused direct economic loss to consumers and TTPs” because they “paid to replace the recalled VCDs with substitute drugs, effectively paying twice for drugs intended to treat the same medical conditions” when they should have only paid once. We must examine these allegations from a “number of different angles in order to see if the purported injury can be framed in a way that satisfies Article III.” *In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Practices & Liab. Litig.*, 903 F.3d 278, 282 (3d Cir. 2018) (citing *Finkelman v. Nat'l Football League*, 810 F.3d 187, 197 (3d Cir. 2016)). Based on these allegations, Plaintiffs' seem to posit at least three theories of economic injury: (1) receipt of a worthless product because of the failure to receive the benefit of their bargain;² (2) receipt of a less valuable product because of the failure to receive the benefit of their bargain;³ and (3) economic loss from having to purchase replacement medication due to the voluntary recalls.⁴

Plaintiffs' first and third theories of economic harm satisfy Article III's injury in fact requirement, but the second fails to allege facts which would permit a factfinder to value the purported injury with resorting to mere conjecture. Under the first theory, they allege the economic benefit they received from Defendants' VCDs was worth less than the economic benefit for which they bargained because the VCDs were contrary to Defendants' representations and warranties. More precisely, Plaintiffs allege Defendants' VCDs were “worthless” because they bargained for a pure, unadulterated, properly branded, and cGMP compliant generic drug but received an impure, adulterated, misbranded, non cGMP compliant, and illegal generic drug. These allegations, like the allegation in *Cottrell* and *Finkelman* after remand, are sufficient for a factfinder to determine the Plaintiffs suffered at least some economic injury because they show Plaintiffs received a less valuable product.

The *Cottrell* plaintiffs set forth sufficient factual allegations that, if proven true, would permit a factfinder to determine that they suffered at least *some* economic injury because they were unable to use a portion of the eye-drop medication they purchased and provided an economic theory that valued that unused portion. After remand, one of the plaintiffs in *Finkelman* accomplished the same by offering an

² This allegation along with the allegation that the VCDs were worth less than their purchase price can also be construed as an allegation that the Plaintiffs suffered economic loss by purchasing drugs for an inflated price. See *Finkelman v. Nat'l Football League*, 810 F.3d 187, 197, 199 (3d Cir. 2016).

³ Plaintiffs allegation is somewhat unclear. They allege “[a]t a minimum, adulterated, misbranded, and/or unapproved VCDs were worth less than their non-contaminated equivalents.” It is unclear whether this means the contaminated VCDs were worth less than their branded counterparts (e.g., Diovan) or whether the VCDs were worth less than an uncontaminated VCD.

⁴ This allegation is also unclear. It is uncertain whether Plaintiffs' theory of economic injury is the full purchase price of the new medication or the difference in cost between the VCDs and the new medication.

analysis by an economist who explained how the NFL's ticketing practice allegedly resulted in increased resale prices. In *Johnson*, the plaintiff failed to satisfy this minimal requirement because she did not provide sufficient facts which would allow a factfinder to determine that she suffered an economic injury from purchasing improperly labeled Baby Powder. Put differently, she did not explain how purchasing improperly labeled baby powder caused her an economic injury other than merely calling it that. Here, Plaintiffs have explained how purchasing the VCDs caused them to suffer an economic injury by presenting a concrete theory of economic loss—the VCDs were worthless or had no market value because contrary to Defendants' representations, they were adulterated, misbranded, non cGMP compliant, and illegal to sell.⁵

Indeed, other courts have found similar theories of economic loss to constitute an injury in fact. *Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1085 (11th Cir. 2019) (concluding plaintiffs suffered an injury in fact when they purchased an adulterated dietary supplement and therefore economically worthless); *Blue Cross Blue Shield Ass'n v. GlaxoSmithKline LLC*, 417 F. Supp. 3d 531, 554 (E.D. Pa. 2019) (reasoning plaintiffs had established an injury in fact because they alleged they paid for drugs "believing they were manufactured in compliance with cGMPs but received drugs that were non-compliant and therefore worth less than what they paid."); *In re Aqua Dots Prod. Liab. Litig.*, 654 F.3d 748, 751 (7th Cir. 2011) (concluding purchasers of a defective toy suffered an injury in fact because they paid more for the toys than they would have, had they known the beads poisoned children); *Franz v. Beiersdorf, Inc.*, 745 F. App'x 47, 49 (9th Cir. 2018) (explaining consumers suffered an injury in fact when they spent money to purchase a skin lotion that should not have been sold because it was illegal to sell the product).

A comparison of the factual circumstances in *Johnson* to this case further reinforces this point. There the plaintiff made three fatal mistakes. First, she merely alleged that "had she been properly informed that using Baby Powder could lead to an increased risk of developing ovarian cancer, she would not have purchased the powder in the first place"; an allegation of buyer's remorse. *In re Johnson*, 903 F.3d at 282. Second, she failed to allege that the Baby Powder "provided her with an economic benefit worth one penny less than what she paid." *Id.* at 288. Third, while she argued she was promised a safe product and received an unsafe one, she never alleged that she developed cancer or was at a risk of developing cancer. *Id.* at 289. Instead, her allegations amounted to a claim that she should be able to sue because others did not receive the benefit of their bargain. *Ibid.* Here, as Defendants point out, Plaintiffs make an allegation of buyer's remorse when they allege that "had they known the product was not the

⁵ Defendants contend Plaintiffs invocation of the FDCA as a basis for Article III standing confirms their claims are an attempt to undertake private enforcement of the FDCA and such an argument is in direct contravention of 21 U.S.C. § 337(a). We already addressed this argument in our first opinion and rejected it. Moreover, even if we were to agree with Defendants, "a valid claim for relief is not a prerequisite for standing." *Cottrell v. Alcon Labs.*, 874 F.3d 154, 166 (3d Cir. 2017); *Steel Co.*, 523 U.S. at 96, 118 S.Ct. 1003 (explaining that "the nonexistence of a cause of action was no proper basis for a jurisdictional dismissal" and highlighting the "fundamental distinction between arguing" that plaintiffs have no cause of action and arguing that they do not have Article III standing).

same as the brand-name drug, they would not have paid for it.” But this is not fatal as it was in *Johnson* because Plaintiffs also allege the VCDs provided them with an economic benefit worth less than what they paid—that is, no economic benefit. Moreover, Plaintiffs did not commit the third mistake the *Johnson* plaintiff did. Here, their economic loss allegations stand on well-pleaded facts and are personal as to them. For instance, they allege the VCDs were misbranded because the labels did not list NDMA and NDEA as active ingredients and adulterated because the presence of NDMA and NDEA reduced the purity or quality of the VCDs. Likewise, the named Plaintiffs allege they “purchased a product that was not the same as the RLD” and as such, are not attempting to sue because others have suffered injuries. Accordingly, Plaintiffs have alleged facts that would permit a factfinder to determine the economic benefit they received in purchasing the VCDs was worth less than the bargained-for economic benefit.

Additionally, this theory of economic loss “would permit a factfinder to value the purported injury at something more than zero dollars without resorting to mere conjecture.” *In re Johnson & Johnson Talcum Powder Prods. Litig.*, 903 F.3d 278, 285 (3d Cir. 2018). Under this theory, Plaintiffs seek reimbursement for the full amount paid for the VCDs, that is, their out-of-pocket expenditures. This is not some amorphous allegation of an economic loss lacking a concrete way of calculating it. This allegation suffices for a factfinder to value Plaintiffs’ purported economic injury. T

The second theory of economic loss, the receipt of a less valuable product, would have sufficed to establish an injury-in-fact if Plaintiffs had provided a theory for the factfinder to value it,⁶ but they do not. Instead, they would have the factfinder resort to mere conjecture to value their purported injury. This second theory is insufficient to confer standing.

However, the third theory of economic injury, the difference between the cost of the VCDs and the replacement drugs, does suffice to confer standing. *Am. Fed’n of State Cty. & Mun. Employees v. Ortho-McNeil-Janssen Pharm., Inc.*, No. 08-CV-5904, 2010 WL 891150, at *3 (E.D. Pa. Mar. 11, 2010) (finding plaintiffs allegation that as a result of the product recall they have paid or will pay expenses related to the purchase of and reimbursement for a substitute product pled a concrete, particular, and traceable economic loss sufficient to establish injury in fact); *Kwikset Corp. v. Superior Court*, 51 Cal. 4th 310, 323, 246 P.3d 877, 886 (2011) (noting an economic injury includes instances where an individual is “required to enter into a transaction, costing money or property, that would otherwise have been unnecessary).

As Defendants point out, Plaintiffs effectively concede the VCDs performed their intended function—lowering blood pressure—when they allege the “FDA advised patients to continue taking VCDs

⁶ See *Cottrell v. Alcon Labs.*, 874 F.3d 154, 168 (3d Cir. 2017).

. . . because of the risks associated with untreated high blood pressure.” However, this does not mean Plaintiffs did not suffer an economic injury.⁷

First, Defendants’ attempt to cabin the economic injury is directly contrary to Third Circuit precedent. Defendants argue, unless Plaintiffs allege they were physically harmed by a product or that it failed to provide its anticipated benefit, there is no economic injury in fact. This is just not true. In *Koronthaly v. L’Oreal USA, Inc.*, the Third Circuit concluded that “[a]bsent any allegation that [the plaintiff] received a product that failed to work for its intended purpose or *was worth objectively less than what one could reasonably expect*,” the plaintiff has not demonstrated a concrete injury-in-fact. 374 F. App’x 257, 258 (3d Cir. 2010) (emphasis added). Although not binding precedent, in *Johnson*, the Third Circuit found the reasoning in *Koronthaly* to be consistent with its holding there. *In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Practices & Liab. Litig.*, 903 F.3d 278, 290 n.15 (3d Cir. 2018). Moreover, language in *Johnson* directly contradicts Defendants’ position. See *In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Practices & Liab. Litig.*, 903 F.3d 278, 281 n.4, 281–82 (3d Cir. 2018). Moreover, Defendants’ argument does not square with *Cottrell* either—a case in which the Third Circuit concluded the plaintiffs had standing even though the product provided its anticipated benefit and did not cause any physical harm. See *Cottrell v. Alcon Labs.*, 874 F.3d 154, 160 (3d Cir. 2017). Quite clearly then, an economic injury is not as limited in the way Defendants define it.

Second, Plaintiffs’ theory of injury-in-fact, that they did not receive the benefit of their bargain, is not based solely on the effectiveness of the VCDs. Plaintiffs’ also bargained for VCDs that were unadulterated, properly branded, cGMP compliant and therapeutically equivalent to their brand-name counterparts—benefits they allegedly did not receive. Thus, Plaintiffs are like “a parent who purchases organic food that turns out to not be organic, a consumer who purchases locksets marketed as being ‘Made in the U.S.A’ that ultimately were not so made, [or] an observant Jew who purchases non-kosher meat that was improperly labeled as being kosher.” *In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Practices & Liab. Litig.*, 903 F.3d 278, 289 n.13 (3d Cir. 2018). Each failed to receive the benefit of their bargain and consequently “received a product that . . . was worth objectively less than what one could reasonably expect.” *Koronthaly v. L’Oreal USA, Inc.*, 374 F. App’x 257, 258 (3d Cir. 2010).

Third, whether Plaintiffs’ concession undermines their claim that the VCDs were “worthless” amounts to an attack on the merits. *Varner v. Domestic Corp.*, No. 16-22482-CIV, 2017 WL 3730618, at

⁷ This concession also does not bring Plaintiffs’ benefit of the bargain theory within the precedential reach of *Thorne*. There was nothing objectively wrong with the tires in *Thorne* as they functioned properly and were not recalled. Thus, the plaintiff’s attempt to characterize a regulatory violation as an economic injury was insufficient. Here, there was something objectively wrong with the VCDs: they were contaminated with carcinogens and consequently recalled. Moreover, the plaintiff’s theory of economic harm in *Thorne* did not depend on the defendant’s representations and warranties like the Plaintiff’s does here. *Thorne v. Pep Boys Manny Moe & Jack Inc.*, 980 F.3d 879, 888 (3d Cir. 2020) (noting the plaintiff did not allege that she was “told at the point of sale that Pep Boys would take steps to help register the tires.”).

*6 (S.D. Fla. Feb. 7, 2017) (concluding whether the plaintiffs could actually prove the refrigerators were worthless when some plaintiffs used them for years amounts to an attack on the merits). The Supreme Court has made clear that in assessing whether the plaintiff has carried his burden of establishing Article III standing, “we separate our standing inquiry from any assessment of the merits of the plaintiff’s claim . . . [and] assume for the purposes of . . . standing . . . that a plaintiff has stated valid legal claims.” *Cottrell v. Alcon Labs.*, 874 F.3d 154, 162 (3d Cir. 2017). Given the constraints on our ability to subject Plaintiffs’ claims to additional scrutiny at this point, we are satisfied that they have alleged an injury-in-fact.

3.1.2 Injury in Fact for Medical Monitoring Complaint

Defendants contend the MMMC fails to allege a concrete injury in fact because the allegation that consumers were allegedly “exposed to a non-bargained for carcinogenic agent . . . that . . . may give rise to future potential health consequences” is speculative future harm insufficient to confer standing. Plaintiffs, on the other hand, argue the Third Circuit has unequivocally determined in medical monitoring cases that exposure to contaminated products or a medical device with a risk of failure constitutes an injury-in-fact. We agree with Plaintiffs.

It is well settled that exposure to toxic substances is sufficient for purposes of Article III standing. *Reilly v. Ceridian Corp.*, 664 F.3d 38, 45 (3d Cir. 2011) (reasoning “exposure to a toxic substance causes injury; cells are damaged and a disease mechanism has been introduced.”); *Carlough v. Amchem Prods., Inc.*, 834 F.Supp. 1437, 1447, 1454 (E.D.Pa.1993) (holding that persons who have been exposed to asbestos but do not manifest any asbestos-related conditions “have alleged sufficient injury in fact” to seek medical monitoring); *Brown v. C.R. Bard, Inc.*, 942 F. Supp. 2d 549, 552 (E.D. Pa. 2013) (concluding the plaintiffs had suffered an injury in fact sufficient for their medical monitoring claims because they alleged the filters implanted in them were at risk of fracturing at some point in the future); see *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d at 851, 851–852 (explaining that “persons exposed to toxic chemicals emanating from the landfill have an increased risk of invisible genetic damage and a present cause of action for their injury” because “in a toxic age, significant harm can be done to an individual by a tortfeasor, notwithstanding latent manifestation of that harm.”). Plaintiffs’ allegations that they consumed VCDs contaminated with carcinogens and thereby suffered genetic and cellular damage easily satisfy Article III’s requirement that they allege an “identifiable trifle” of an injury.

Defendants’ argument is that because *a part of one sentence* in Plaintiffs’ one hundred fifty-four-page complaint makes a speculative claim of harm, their whole complaint should be dismissed. This ignores the numerous allegations in the complaint that the named Plaintiffs consumed VCDs contaminated with NDMA or NDEA and thereby were exposed to carcinogens. Moreover, Defendants’ arguments conflate the legal sufficiency of Plaintiffs’ causes of action with Article III standing. *Carlough*

v. Amchem Prod., Inc., 834 F. Supp. 1437, 1450 (E.D. Pa. 1993) (explaining “the question of whether the exposure-only plaintiffs have standing to bring this lawsuit in federal court does not depend on whether they have stated a valid cause of action under applicable tort law.”).

3.1.2.1 Traceability⁸

According to the Manufacturer Defendants, Plaintiffs’ injuries are not fairly traceable to all Defendants challenged conduct and therefore the ELMC and MMMC should be dismissed because they do not satisfy Article III standing. Specifically, there are twenty Defendants in the ELMC as to whom no class representative alleges a traceable injury; likewise, there are twenty-five Defendants in the MMMC as to whom no class representative alleges a traceable injury. In a similar vein, the Wholesaler Defendants contend Plaintiffs have not established the Article III traceability requirement as to them because there are no allegations that the Wholesalers were a but for cause of or a substantial factor in causing the purported injuries nor are there allegations that they had direct influence or control over the manufacturing processes. They also reject the argument that traceability can be satisfied by a market share theory because it has been rejected in products liability cases. Plaintiffs maintain they have met the traceability requirement for the Manufacturer Defendants because they pled “facts that show how Manufacturer Defendants’ assurances and representations were part of the bargain underlying their purchases of VCDs.” With respect to the Wholesaler Defendants, Plaintiffs argue traceability has been satisfied under a market share theory because the “three major wholesalers are responsible for supplying Defendants’ VCDs to retail pharmacies across the nation and comprise over 90% of the wholesaler market.”

The second requirement of Article III standing is “traceability.” *Pitt News v. Fisher*, 215 F.3d 354, 360 (3d Cir.2000). To satisfy this requirement, the plaintiff must establish that “the defendant’s challenged actions, and not the actions of some third party, caused the plaintiff’s injury.” *See Lujan*, 504 U.S. at 560, 112 S.Ct. 2130. This causal connection need not be as close as the proximate causation needed to succeed on the merits of a tort claim. *See Pub. Interest Research Group of N.J., Inc. v. Powell Duffryn Terminals Inc.*, 913 F.2d 64, 72 (3d Cir.1990). Rather, an indirect causal relationship will suffice so long as there is “a fairly traceable connection between the alleged injury in fact and the alleged conduct of the defendant.” *Vt. Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 771 (2000).

This inquiry does not change in the context of a putative class action. “That a suit may be a class action . . . adds nothing to the question of standing, for even named plaintiffs who represent a class ‘must allege and show that they personally have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong and which they purport to represent.’” *Lewis v.*

⁸ Contrary to Plaintiffs’ contention, Retailers do contest traceability as they incorporate the Manufacturers’ standing arguments.

Casey, 518 U.S. 343, 357 (1996) (quoting *Simon v. Eastern Ky. Welfare Rights Org.*, 426 U.S. 26, 40 n.20 (1976)). In other words, standing cannot be predicated on an injury which the plaintiff has not suffered, nor can it “be acquired through the back door of a class action.” *Allee v. Medrano*, 416 U.S. 802, 828–29 (1974). Thus, in order to establish standing in the class action context, for each named defendant, at least one named plaintiff must be able to allege an injury traceable to that defendant. *In re Franklin Mut. Funds Fee Litig.*, 388 F. Supp. 2d 451, 461 (D.N.J. 2005), as amended (Sept. 22, 2005). An inability to do so with regard to certain named defendants demonstrates an absence of standing as to claims asserted against those defendants. *Id.*; see also *Haas v. Pittsburgh Nat. Bank*, 526 F.2d 1083, 1096 n.18 (3d Cir. 1975) (noting that in the context of class actions instituted by a plaintiff against multiple defendants, the nominal plaintiff may not maintain an action on behalf of the class if he or she cannot assert an individual cause of action against that defendant).

For instance, in *In re Franklin Mut. Funds Fee Litig.*, shareholders of the Franklin and Templeton Mutual Funds brought a class action against Franklin Resources, Inc., and its subsidiaries and affiliates for charging excessive fees, disseminating materially false and misleading information, and improperly paying brokers to steer unsuspected investors into the funds. *In re Franklin Mut. Funds Fee Litig.*, 388 F. Supp. 2d 451, 461 (D.N.J. 2005), as amended (Sept. 22, 2005). The named plaintiffs were shareholders in three mutual funds but also sought to maintain a class action on behalf of all investors who owned shares in over 100 different mutual funds. *Id.* at 456. The Court dismissed the plaintiffs’ claims against the one hundred other fund defendants because the named plaintiffs did not assert an injury that was traceable to these funds. *Id.* at 461. It reasoned that “if the named plaintiffs cannot or do not assert their own direct claim against a named defendant, they may not bring a claim against that defendant on behalf of other investors.” *Id.* Thus, because the plaintiffs did not link an investment adviser defendant, distributor defendant, or director defendant to a particular fund, the court could not tell whether the named plaintiffs’ injuries were fairly traceable to the defendants’ alleged misconduct and consequently whether they had standing to sue the funds. *Id.* at 463.

The same rationale applies here. Plaintiffs have failed to trace their injuries to many of the Defendants in this case beyond conclusory allegations that lump Defendants together. For instance, in the ELMC, Plaintiffs’ allege “[w]holesaler Defendants expressly or impliedly warranted VCDs they sold were not adulterated, misbranded, or contaminated, when in fact that was not the case.” Likewise, they allege that many Defendants “distributed contaminated, adulterated and/or misbranded VCDs in the United States, including in the State of New Jersey.” These allegations do not show that one of the named Plaintiffs has alleged an injury that is traceable to each of the named Defendants. Put differently, these allegations and the allegations like them do not show that the named Plaintiffs can assert their own direct claim against a named Defendant. The same holds true with respect to the allegations for the Retailer Defendants. In fact, the very case Plaintiffs cite, *Debernardis v. IQ Formulations, LLC*, 942 F.3d

1076, 1088 (11th Cir. 2019), actually support this conclusion. In *Debernardis* the Court held the plaintiffs' economic losses were fairly traceable to the defendant because their *factual allegations* supported an inference that it distributed the supplements. *Id.* at 1088. The complaint alleged only two entities supplied the supplements to consumers: IQ and Europa. *Id.* IQ, the manufacturer, sold its supplements to Europa, its exclusive distributor, who in turn sold them to retailers. *Id.* at 1089. The plaintiffs alleged that Europa supplied Walgreens with supplements and that they had purchased supplements from Walgreens. *Id.* Thus, the Court concluded the allegations were sufficient to support an inference that defendants supplied the supplements which plaintiffs purchased. *Id.*

Debernardis then does not stand for the proposition that an injury can be fairly traced to a distributor simply because of its dominant position in the market but rather stands for the proposition that named plaintiffs must allege facts that show their injuries are fairly traceable to each defendants' conduct. Missing here are those allegations. We cannot conclude the named Plaintiffs injuries are attributable to AmerisourceBergen Corporation from the allegation that it sold "a large portion of the adulterated and/or misbranded VCDs that were ultimately paid for by U.S. consumers." Therefore, Plaintiffs have failed to satisfy the traceability requirement for purposes of Article III standing with respect to the Defendants listed in the Manufacturer Defendants' charts.

However, Plaintiffs will be given the opportunity to amend their Complaint and properly plead the bases for asserting claims against specific Defendants. Because Plaintiffs should be able to amend their Complaints with relative ease to satisfy this requirement, the Court will continue onward and consider the other arguments raised by Defendants.

3.1.2.2 Standing to Bring Claims Across All States

Defendants argue that because a class representative only has standing to sue under the laws of the state where he or she resides, and the class representatives here are asserting claims under laws of states where they do not, these claims should be dismissed. Plaintiffs, on the other hand, contend they may properly bring claims on behalf of out of state putative class members because only the class representatives need to have standing, and that Defendants are improperly injecting class certification issues into the standing inquiry.

Plaintiffs are correct that "unnamed, putative class members need not establish Article III standing,"⁹ so long as the class representatives have standing. However, this does not squarely address the issue before the Court. *Ponzio v. Mercedes-Benz USA, LLC*, 447 F. Supp. 3d 194, 224 (D.N.J. 2020).

⁹ *Neale v. Volvo Cars of N. Am., LLC*, 794 F.3d 353, 362 (3d Cir. 2015)

The issue is whether the *named* plaintiffs have standing to assert their claims, and more precisely, whether they have standing to assert claims under the laws of states where they do not reside and were not injured; and the answer flowing from Supreme Court precedent would be no. The Supreme Court's standing cases have made two principles of law clear: first, a plaintiff must demonstrate standing for each claim he seeks to press; and second, class actions do not change the requirements of standing. *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 337 (2006); *Lewis v. Casey*, 518 U.S. 343, 357 (1996). The implication of these two principles is "that standing is not dispensed in gross, [and therefore] a [named] plaintiff who raises multiple causes of action must demonstrate standing for each claim." *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 245 (3d Cir.2012).

Plaintiffs have not satisfied this burden. The MMMC and ELMC assert state specific claims under the laws of all fifty states, and the District of Columbia and Puerto Rico. Yet, named Plaintiffs, collectively, represent only twenty-one states—New York, New Mexico, North Carolina, South Carolina, New Jersey, Texas, Indiana, Pennsylvania, California, Ohio, Massachusetts, Mississippi, Florida, Virginia, Louisiana, Kansas, Georgia, Connecticut, West Virginia, Maryland, and Illinois. As named Plaintiffs neither reside in nor have alleged they suffer an injury in thirty-one other states and territories, their claims in these jurisdictions will be dismissed without prejudice for want of standing.

Plaintiffs' reliance on *Mielo v. Steak 'n Shake Operations, Inc.*, 897 F.3d 467, 474 (3d Cir. 2018) does not support their contentions. As Defendants note, the *Mielo* named plaintiffs asserted claims under one federal statute, the American with Disabilities Act. Although courts have found plaintiffs can assert federal claims on behalf of a nationwide class (*Ponzio v. Mercedes-Benz USA, LLC*, 447 F. Supp. 3d 194, 224 (D.N.J. 2020)), the named Plaintiffs here raise no federal cause of action but state statutory or common law claims. Their claim under the Magnuson-Moss Warranty Act does not help as it relies on the underlying state law claims. *Ponzio v. Mercedes-Benz USA, LLC*, 447 F. Supp. 3d 194, 224 (D.N.J. 2020) (citing *Johansson v. Cent. Garden & Pet Co.*, 804 F. Supp. 2d 257, 265 (D.N.J. 2011)).

Conclusion

For the reasons expressed above, Defendants' Motions to Dismiss are **GRANTED** in part. Plaintiffs have up and including 27 January 2021 to move to amend.

Dated: 12 January 2021

/s Robert B. Kugler
ROBERT B. KUGLER
United States District Judge